

Effects of high dose vitamin D supplementation on muscle mass and muscle strength in frail elderly people

Submission date 11/04/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 11/04/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 07/04/2011	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr C Oudshoorn

Contact details
Erasmus Medical Centre
Room D442
P.O. Box 2040
Rotterdam
Netherlands
3000 CA
+31 (0)10 463 5037
c.oudshoorn@erasmusmc.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Study objectives

Vitamin D improves muscle-mass and -strength which improves overall quality of life in patients with low serum vitamin D levels.

Please note that as of 13/07/10 this record was updated to included changes made to the protocol during the planning phase of the trial (i.e. between the time of registration and the beginning of the recruitment phase). All updates can be found in the relevant field with the above update date.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added 13/07/10:

The Medical Ethics Review Committee (Medisch Ethische Toetsings Commissie), Erasmus Medical Centre approved on the 24th of July 2007 (ref: MEC-2007-160)

Study design

Randomised placebo controlled parallel group double blind trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

Copies of the Investigational Medicinal Product Dossier (IMPD) and 2007 MEC approval are available on request. Please use contact details below.

Health condition(s) or problem(s) studied

Hypovitaminosis D on muscle mass and strength

Interventions

Current information as of 13/07/10:

Patients were randomised to receive either

1. 1800IU cholecalciferol (vitamin D3) daily

2. Placebo daily

Medications were used for a period of six months. The end date for inclusion into this trial was December 2009.

Initial information at time of registration

Individuals are randomised to receive either:

1. 1200 IU vitamin D/day and 1000 mg calcium/day
2. Placebo medications and 1000 mg calcium/day

Medications will be used for a period of six months.

Intervention Type

Supplement

Phase

Not Specified

Drug/device/biological/vaccine name(s)

High dose vitamin D

Primary outcome measure

Differences in muscle strength (handgrip strength and quadriceps strength) between treatment and control group.

Secondary outcome measures

1. Changes in mobility:
 - 1.1. Timed up and go test
 - 1.2. Walking distance
2. Quality of life (using the health assessment questionnaire)
3. Falls

Overall study start date

01/04/2007

Completion date

01/04/2008

Eligibility

Key inclusion criteria

1. Frail elderly people, aged greater than 65 years
2. Living in homes for the elderly
3. Serum vitamin D level less than 50 nmol/l

Added 07/04/2011:

- 4: Stable health (including no history of recurrent falling or recent fracture).

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

300

Key exclusion criteria

1. Not able to perform muscle strength measurements
2. History of kidney stones, renal insufficiency (less than 40%)
3. Primary hyperparathyroidism
4. Dementia (Mini Mental State Examination [MMSE] less than 20/30 points)
5. Life expectancy less than six months
6. Neurodegenerative disorders (Parkinsons, Amyotrophic Lateral Sclerosis [ALS])
7. Use of the following medications:
 - 7.1. Vitamin D
 - 7.2. Bisphosphonates
 - 7.3. Steroids

Date of first enrolment

01/04/2007

Date of final enrolment

01/04/2008

Locations

Countries of recruitment

Netherlands

Study participating centre

Erasmus Medical Centre

Rotterdam

Netherlands

3000 CA

Sponsor information

Organisation

Erasmus Medical Centre (Netherlands)

Sponsor details

Department of Geriatrics

P.O. Box 2040

Rotterdam
Netherlands
3000 CA

Sponsor type

Hospital/treatment centre

Website

<http://www.erasmusmc.nl/>

ROR

<https://ror.org/018906e22>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Erasmus Medical Centre (Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration